IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Anthony Lemus et al.	Confirmation No.:		4433
Appln. No.	:	10/002,038	Art Unit	:	1743
Filed	:	November 2, 2001	Examiner	:	L.I.Cross
Title	:	VARIABLE RESISTANCE STERILIZATION PROCESS CHALLENGE DEVICE AND METHOD			

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AMENDED
APPEAL BRIEF

I. Real Party in Interest

This application is assigned, via an assignment recorded at reel 012656, frame 0373, to Ethicon, Inc., which is owned by Johnson & Johnson.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of Claims

Claims 1 to 21 form the basis for this appeal. Each of claims 1 to 21 stands rejected.

IV. Status of Amendments

No amendments have been filed after issuance of the Office Action Mailed December 29, 2004.

V. Summary of Claimed Subject Matter

A sterilization process challenge device according to the present invention comprises a sterilization indicator contained within a container and a variable diffusion restriction into the container. [see specification page 3, lines 19 to 22; page 7, lines 11 to 29]

The sterilization indicator can be a biological indicator or a chemical indicator indicative of a chemical sterilant. [see specification page 11, lines 10 to 22]

The variable diffusion restriction can comprise a diffusion path into the container which can comprise an adjustable covering for the path to block or unblock portion of the diffusion path. In one embodiment of the invention, the container comprises a first member and second member disposed in telescoping relation with the openings disposed on the first member and the second member forming the adjustable covering. [see specification page 7, lines 11 to 29 and FIG. 1]

The diffusion path can comprise a plurality of openings, which can be different in size. At least one opening is preferably covered with a removable covering. Rather than, or in addition to multiple openings, the diffusion path can comprise a slot, portions of which can be covered or uncovered to vary the diffusion resistance. [see specification page 8, line 22 to page 9, line 21 and FIGS. 3 and 4]

The diffusion path can comprise a long narrow path, wherein the diffusion path can be adjusted by trimming the length of the path. The diffusion path can comprise two or more materials wherein the materials have different capabilities to retain sterilant. The diffusion path can comprise a sterilant absorber such that the amount of sterilant diffusing to the indicator can be adjusted by the type or the size of the absorber. [see specification page 9, line 23 to page 10, line 23 and FIG. 5]

A method for assessing the sterilization efficacy of a sterilization process according to the present invention comprises the steps of: placing a sterilization process challenge device in proximity to a device to be sterilized during the sterilization process, the

sterilization process challenge device comprising a container, a sterilization indicator within the container, an opening into the container and an adjustable diffusion restriction at the opening; assessing a feature of a load of one or more devices to be sterilized in the sterilization process; adjusting the amount of diffusion restriction provided by the diffusion restriction based upon the feature of the load; and indicating the sterilization efficacy with the indicator. [see specification page 4, line 27 to page 5, line 13; page 12, line 10 to page 13, line 6]

The step of adjusting the amount of diffusion restriction can comprise adjusting an area of the opening into the container, such as by covering or uncovering the opening into the container. The opening can comprise a plurality of apertures in a wall of the container. [see specification page 5, lines 15 to 19; page 7, lines 11 to 28]

The diffusion restriction can comprise a path into the container and the step of adjusting the amount of diffusion restriction can comprise adjusting the length of the path. [see specification page 5, lines 21 to 24; page 9, line 23 to page 10, line 3]

The step of adjusting the diffusion restriction can comprise adjusting an amount of absorbent material placed adjacent the indicator. [see specification page 5, lines 26 to 28; page 10, line 25 to page 11, line 8, and FIG. 6]

The indicator can indicate whether a reference organism remains viable or whether a sufficient amount of a sterilizing gas was present during the sterilization process. [see specification page 6, lines 2 to 5; page 11, lines 10 to 22]

VI. Grounds of Rejection to be Reviewed on Appeal

A. Whether Hendricks et al. anticipate claims 1 to 5, 7, 11 to 15 and 18 to 21 under 35 U.S.C. § 102(b)?

B. Whether the Examiner has established a prima facie case of obviousness under 35 U.S.C. § 103(a) in rejecting claims 6, 8 to 10, 16 and 17 over Hendricks et al. and Falkowski et al.?

VII. Argument

A. Whether Hendricks et al. anticipate claims 1 to 5, 7, 11 to 15 and 18 to 21 under 35 U.S.C. § 102(b)?

The Examiner failed to establish anticipation under 35 U.S.C. § 102(b) in rejecting claims 1 to 5, 7, 11 to 15 and 18 to 21 over Hendricks et al. The Examiner points to column 4, lines 44-52 and to column 7 lines 5 to 13 and lines 45 to 57 of Hendricks et al. as support for her contention that Hendricks et al. teaches a variable diffusion restriction. However, these paragraphs all discuss how to vary a manufacturing process to produce a challenge device with a different, yet fixed, resistance to diffusion. Parameters can always be varied during manufacture to produce varying degrees of performance in any product. Hendricks et al. merely teach an easy way to vary a property during manufacture. However, once that product is manufactured it is a product with a fixed, not variable, resistance and therefore fails to anticipate the claimed invention. Accordingly, Hendricks et al. fails to anticipate the claimed invention.

Claim 5 defines the variable diffusion restriction as comprising a diffusion path into the container which has an adjustable covering for the path to block or unblock a portion of the diffusion path. The Examiner points to the length of the plug being varied during manufacture as anticipatory. However, that fails to reach the limitation of blocking or unblocking a portion of the diffusion path.

Claim 11 defines the variable diffusion restriction as comprising a long narrow path adjusted by trimming the length of the path. The Examiner again points to the length of the plug being varied during manufacture as anticipatory. This does not anticipate a long narrow path adjusted by trimming its length.

Claim 15 defines the adjustment of the diffusion restriction a comprising adjusting the area of an opening into the container. Hendricks et al. fail to teach this limitation.

Claim 18 defines the process of adjusting the diffusion restriction to comprise adjusting the length of a diffusion path into the container. Hendricks et al. fail to teach this step.

B. Whether the Examiner has established a prima facie case of obviousness under 35 U.S.C. § 103(a) in rejecting claims 6, 8 to 10, 16 and 17 over Hendricks et al. and Falkowski et al.?

The Examiner has failed to establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in rejecting claims 6, 8 to 10, 16 and 17 over Hendricks et al. and Falkowski et al. Falkowski et al. add little to the teaching of Hendricks et al. Falkowski et al. do teach multiple openings into the container which may be either all opened or all closed, but not partially opened. Hendricks et al. employ a foam plug in an open end of a tube through which to pass sterilant gas and therefore would have no need for the holes of Falkowski et al. They remove the plug to add a precise amount of water for incubation. If they substituted the holes of Falkowski et al. adding a precise amount of water would be more difficult. There would be no motivation for such an awkward combination. There is no suggestion for making the alleged combination. The only teaching or suggestion otherwise comes from Applicants' specification.

The Examiner argues that the "mere operation of the device" suggests adjustable covering. Applicants respectfully submit that this is hindsight reconstruction at its finest. Falkowski et al. teach either all of the openings being occluded or none of the openings being occluded and nothing in between. Accordingly, More importantly, all of the openings are open during sterilization and they are occluded only afterward to provide a liquid tight closure during incubation.

Claim 6 defines a telescoping relationship which to adjustably cover the opening. Even if the alleged combination were made it would not reach this claimed invention as Falkowski et al. as such combination would not teach adjustable covering of the opening.

Claim 8 defines a plurality of openings of different sizes, which is not taught by either reference.

Claim 10 defines the opening being a slot, which is not taught by either reference.

Claim 16 defines a method for assessing sterilization efficacy in which an amount of diffusion is adjusted by covering or uncovering an opening into the container. This is not taught by the references. Neither would the alleged combination reach this as at best it would provide an opening which can be covered (and not adjustably) after the diffusion is completed.

Applicants submit that the Examiner has failed to establish anticipation or a prima facie case of obviousness and request withdrawal of the rejections and allowance of the claims.

Respectfully submitted,

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Claims Appendix

Claims on Appeal

1. A sterilization process challenge device comprising:

a sterilization indicator contained within a container; and

a variable diffusion restriction into said container.

2. A sterilization process challenge device according to claim 1 wherein the sterilization indicator is a biological indicator.

3. A sterilization process challenge device according to claim 1 wherein the sterilization indicator is a chemical indicator indicative of a chemical sterilant.

4. A sterilization process challenge device according to claim 1 wherein the variable diffusion restriction comprises a diffusion path into said container.

5. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises an adjustable covering for said path to block or unblock portion of said diffusion path.

6. A sterilization process challenge device according to claim 5 wherein the container comprises a first member and second member disposed in telescoping relation with a plurality of openings disposed on the first member and the second member forming the adjustable covering.

7. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a plurality of openings.

8. A sterilization process challenge device according to claim 7 wherein openings are different in size.

9. A sterilization process challenge device according to claim 7 wherein at least one opening is covered with a removable covering.

10. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a slot.

11. A sterilization process challenge device according to claim 4 wherein the diffusion path comprises a long narrow path, wherein the diffusion path can be adjusted by trimming the length of the path.

12. A sterilization process challenge device according to claim 11 wherein the diffusion path comprises at least two materials wherein said materials have different capabilities to retain sterilant.

13. A sterilization process challenge device according to claim 4 wherein the diffusion path further comprises a sterilant absorber such that the amount of sterilant diffusing to the indicator can be adjusted by the type or the size of the absorber.

14. A method for assessing the sterilization efficacy of a sterilization process comprising the steps of:

placing a sterilization process challenge device in proximity to a device to be sterilized during the sterilization process, the sterilization process challenge device comprising a container, a sterilization indicator within the container, an opening into said container and an adjustable diffusion restriction at said opening;

assessing a feature of a load of one or more devices to be sterilized in said sterilization process;

adjusting the amount of diffusion restriction provided by said diffusion restriction based upon said feature of said load; and

indicating the sterilization efficacy with the indicator.

15. A method according to claim 14 wherein the step of adjusting the amount of diffusion restriction comprises adjusting an area of the opening into the container.

16. A method according to claim 15 wherein the area of the opening is adjusted by covering or uncovering the opening into the container.

17. A method according to claim 16 wherein the opening comprises a plurality of apertures in a wall of the container.

18. A method according to claim 14 wherein the diffusion restriction comprises a path into the container and the step of adjusting the amount of diffusion restriction comprises adjusting the length of the path.

19. A method according to claim 14 wherein the step of adjusting the diffusion restriction comprises adjusting an amount of absorbent material placed adjacent the indicator.

20. A method according to claim 14 wherein the indicator indicates whether a reference organism remains viable.

21. A method according to claim 14 wherein the indicator indicates whether a sufficient amount of a sterilizing gas was present during the sterilization process.

Evidence Appendix

[NONE]

Related Proceedings Appendix

[NONE]